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A Pilot Study of Continuous Negative Pressure (CNEP) In Bronchiolitis

Submission date 05/03/2004	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 05/03/2004	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 09/08/2021	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A Pilot Study of Continuous Negative Pressure (CNEP) In Bronchiolitis

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Bronchiolitis

Interventions
Infants were randomised to either standard treatment, or standard with CNEP.
Inspired oxygen requirement was measured with a calibrated oxygen analyser placed close to the infant's nose in a headbox, in which the oxygen flow was adjusted to maintain SaO2 96-99% at rest, measured with a Nellcor N-200 pulse oximeter.
When an infant fulfilled the entry criteria, written informed consent was obtained from parents and baseline data was collected.
Patients were then randomised to either conventional therapy or conventional therapy plus CNEP. The randomisation was performed using a stratification scheme to achieve a measure of balance in the treatment groups.
Conventional therapy in these hospitals included the use of additional inspired oxygen and bronchodilators. Infants were intubated and positive pressure ventilation (PPV) was initiated in the presence of respiratory acidosis with a pH below 7.25, hypercapnia, hypoxaemia in spite of additional inspired oxygen, recurrent apnoea and respiratory fatigue.
CNEP was applied using purpose built systems (Horner and Wells Ltd, Chelmsford, UK, and DHB Tools Ltd, Leamington Spa, UK).
Treatment was begun with -4 cmH2O of CNEP. If the FiO2 required to achieve normal SaO2 did not decrease within the next 30 min, CNEP was decreased to -6 cmH2O. Weaning from CNEP was attempted after a treatment period of at least 24 hours and usually in the presence of an FiO2<0.

3.
Infants were fed by either nasogastric tube, or intravenously, according to the degree of respiratory distress.
Heart rate, respiratory rate and FiO2 were recorded hourly if the infants were at rest when they were treated with additional inspired oxygen.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
31/12/2004

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Forty two infants admitted with bronchiolitis, who needed more than 40% oxygen therapy to maintain normal levels of arterial oxygen saturation. This was a pilot study. Forty two patients were enrolled between January 1991 and April 1992 in two paediatric hospitals in England (North Staffordshire Hospital and Royal Berkshire Hospital) if they fulfilled the following criteria:
1. Clinical diagnosis of bronchiolitis (irrespective of whether respiratory syncitial virus was isolated)
2. Age 1 year
3. Presence of respiratory failure with fractional inspired oxygen (FiO2) 0.4 to achieve an arterial oxygen saturation (SaO2) of 96-99%.

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants

Key exclusion criteria
Infants with bronchopulmonary dysplasia (BPD), congenital cardiac, pulmonary or neuromuscular diseases or signs of upper airway obstruction were excluded.

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Department of Paediatrics, University Hospital of North Staffordshire
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Sponsor information

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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
North Staffordshire and Royal Berkshire Hospitals

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration